REMARKS

The application is believed to be in condition for allowance.

There are no formal matters pending.

Claim Rejections - Section 102

The Official Action rejected claims 1, 3-5, 13, and 23-26 under 35 USC 102(b) as being anticipated by Baumgartner (U.S. Publication 2002/0048553; hereinafter "BAUMGARTNER"). This rejection is maintained from the previous Official Action of January 15, 2008 (the "previous Official Action").

In reply to the Applicants' arguments responsive to the previous Office Action, the present Official Action (the "Official Action") states that BAUMGARTNER teaches capsules with coatings, and particles free of covering, and that the reference associates the covering directly to the capsule and not the particle.

The Official Action also states that BAUMGARTNER teaches the capsule as broken open, but does not make this statement as to the particle, and that further, the particle is made of a thixotropic gel and possibly of an active agent (paragraph [0011]), and thereby concludes that the particle has a drug or coloring mixed within a binding material, and therefore meeting the recitations of the amended claims. The Official Action further states that the particles are in toothpaste which

is in a single dose unit when applied to a toothbrush or the teeth.

It is therefore understood that the Official Action identifies the particles of BAUMGARTNER as teaching the semi-solid composition or semi-solid homogeneous gel bead recited in claims 1 and 23, respectively.

Applicants respectfully disagree.

As to claim 1, it is respectfully submitted that BAUMGARTNER does not teach a homogenous and non-encapsulated single-dose gel bead.

On the contrary, BAUMGARTNER teaches a cream replete with tangible particles which may be encapsulated, or simply capsules (e.g., paragraph [0005]; Figure). BAUMGARTNER's composition provides a large number of tiny burstable capsules and/or disruptable particles (paragraph [0006]), comprising only a part of an entire dentifrice composition within a conventional creamy toothpaste (see, e.g., paragraph [0025]). The particles identified by the Examiner as teaching the gel beads recited in claim 1 are thixotropic (i.e., tending to become liquid when stirred or shaken) suspended in a toothpaste medium occupying between 10-50% of the medium by volume (paragraphs [0010], [0012]).

1. BAUMGARTNER makes no teaching of a single dose gel bead, as required by claim 1.

BAUMGARTNER discloses particles measuring "between 0,1 mm and 4 mm, preferably between 0,5 mm and 3 mm or optimally between 1 mm and 2 mm," (paragraph [0009]). BAUMGARTNER makes no disclosure, anywhere in the specification or the drawing figures, teaching or suggesting that such a particle, of any size, forms a single dose of anything.

On the contrary, the Figure clearly discloses a plurality of particles and/or capsules, and the specification consistently refers to the particles in the plural form. BAUMGARTNER further states repeatedly of a lack of means to control how much toothpaste (and particles suspended therein) is squeezed out by a user from a tube onto a toothbrush. This is clearly recognized by BAUMGARTNER as an unsolved problem, especially in relation to fluoride toxicity (see, for example, paragraphs [0003] and [0028]).

Thus, BAUMGARTNER does not anticipate.

2. BAUMGARTNER makes no teaching of a homogeneous gel bead, as required by claim 1.

BAUMGARTNER clearly teaches that the toothpaste is non-homogeneous, teaching a "creamy toothpaste mass" combined with "capsules and/or binding particles are spread uniformly within," (paragraph [0006]).

The capsules are also not homogeneous, as disclosed by paragraphs [0012], [0017], and elements 2 and 3 of the Figure.

The Official Action offers BAUMGARTNER's particles as being homogeneous. It is noted that BAUMGARTNER refers to several distinct elements as "particles" (a "dye particle", paragraph [0022]; "color flavored particles", paragraph [0024]; and "abrasive particles", paragraph [0028]). The particles associated with capsules are referred to in paragraph [0012] as "flavor particles" and elsewhere as merely "particles".

BAUMGARTNER teaches the flavor particles being interchangeable with the capsules (e.g., paragraph [0007]). Flavor particles are distinguished from capsules by "consisting of binding agent" (BAUMGARTNER claim 1) and "tasty ingredients and eventually the dye-stuff or pigment ingredients... are enclosed within capsules or bound in particles of binding agent," (paragraph [0006]). BAUMGARTNER's claim 1 recites that a particle "consists" of binding agent. It follows that the other components, the "tasty ingredients" and "dye-stuff", are distinct from the particle substance (the "binding agent") just as the capsule casing is distinct from the contents of the capsule (paragraph [0008]).

Therefore, BAUMGARTNER make no teaching that the flavor particles, any more than the capsules, are homogeneous.

This conclusion is consistent with the remaining descriptions of the flavor particle ("flavor particles should be stable enough to withstand the production process, storage and removal from the tube," paragraph [0012]; "coloring could be

found within the capsules, in the wall of the capsules, or in the particles made of binding agent," paragraph [0019] emphasis added) and also consistent with the description of the drawing figures, paragraphs [0036] and [0038], expressly stating that the Figure illustrating an encapsulating material surrounding a distinct payload ingredient describes both a capsule and a flavor particle.

There is no alternative teaching, anywhere in the specification or the Figure, in support of a different structure with respect to the particles. Nor is there any teaching as to the flavor or color as having any structure except as a payload distinct from an encapsulating shell.

Moreover, BAUMGARTNER unequivocally teaches that "capsules and/or binding particles... will break open under mechanical influence... to set their tasty and/or colored ingredients free," paragraph [0005] (emphasis added). That is, the mechanical operation is to open the particle to free the payload inside it. One of skill clearly understands from this teaching that both capsules and particles incorporate a boundary layer between an encapsulating portion and a payload encapsulated within.

In contrast, the present invention requires a homogeneous and non-encapsulated gel bead (see claim 1), such as having a cross-section illustrated as element 201 of Figure 2 (see also, e.g., paragraph [0077], and paragraph [0083] expressly

teaching that the homogeneous beads are not structurally equivalent to capsules). A gel bead having a homogeneous, non-encapsulated structure cannot "open" as there is no boundary layer within the gel to distinguish between an inside and an outside. As disclosed by Figure 2, element 201, a single, consistent structure is taught throughout the bead.

Based on the facts outlined above, neither the capsule nor the particle disclosed by BAUMGARTNER teaches this. Therefore, it is respectfully submitted that BAUMGARTNER does not anticipate.

3. BAUMGARTNER makes no teaching of a gel bead comprised of an active ingredient intimately mixed with at least one gelling agent to form a mixed homogeneous composition, as required by claim 23.

As set forth above as to claim 1, none of the toothpaste described by BAUMGARTNER, the capsule, or the flavor particle teaches a homogeneous composition of gelling agent and active ingredient.

Hence, BAUMGARTNER does not anticipate 23 for the same reasons set forth as to claim 1.

4. Withdrawal of the rejection for anticipation is thereby respectfully solicited.

Based on the facts presented above, it is respectfully submitted that the rejection of claims 1 and 23 under 102(b) over BAUMGARTNER is inappropriate.

It is also respectfully submitted that claims depending from claims 1 and 23 are patentable at least for depending from patentable parent claims.

For example, BAUMGARTNER fails to teach the recitations of claim 3. On the contrary, BAUMGARTNER is silent about the composition of the particles. At best, BAUMGARTNER teaches agar with respect to the capsules. However, as presented in the Applicants' response to the previous Office Action, BAUMGARTNER's capsules are not homogeneous and non-encapsulated single-dose gel beads. Hence, none of BAUMGARTNER's capsules or particles anticipates claim 3.

BAUMGARTNER fails to teach the recitations of claim 5. BAUMGARTNER is silent about the composition of the particles cited by the Official Action as anticipating the gel beads of the present invention. Therefore, claim 5 is patentable in its own right over BAUMGARTNER in addition to being dependent from a patentable parent claim.

BAUMGARTNER fails to teach the recitations of claim 8. On the contrary, BAUMGARTNER is silent as to a single dose by weight.

BAUMGARTNER fails to teach the recitations of claims 24-27. Similarly to claim 3, above, BAUMGARTNER is silent about the composition of the particles. At best, BAUMGARTNER teaches agar with respect to the capsules, which fail in their own right to anticipate the present invention.

From all the foregoing, it is respectfully submitted that the claims are patentable over BAUMGARTNER. Reconsideration and withdrawal of the rejection under Section 102 are respectfully requested.

Claim Rejections - Section 103

The Official Action maintains the rejection of the previous Official Action in rejecting claims 1, 5, 7-9, 13, and new claims 23 and 26-27 under 35 USC 103(a) as being unpatentable over Schmidt (U.S. Patent 5,354,551; hereinafter "SCHMIDT") in view of Alexander (WO 2002/026078, English Equivalent U.S. Publication 2004/0091431; hereinafter "ALEXANDER"). This rejection is also maintained from the previous Official Action.

In reply to the Applicants' arguments responsive to the previous Official Action, the Official Action states that the compositions of SCHMIDT are cast into films by applying them to a surface, and therefore it may be concluded that the composition could also be cast into a mold to form a bead.

The Official Action states that the mixture would still remain uniform with the only difference being the shape, and that the active ingredients would be released just as they would in strip form because the active ingredients are released when the outside of a bead shape is dissolved, and therefore the composition would still function as toothpaste.

In particular, the Official Action states that "no matter the shape, it is reasonable to conclude that the composition will perform the same."

Applicants respectfully disagree. The rejection is respectfully traversed as the claims are clearly not obvious. The rejection appears to be a simple hindsight assembly of unrelated references.

The analysis of whether a claim is obviousness begins by the Examiner identifying each of the features taught by the primary reference (in this case, SCHMIDT) that satisfy the recited elements of the independent claim, and then to identify each feature of the claim that is not disclosed by the reference.

The Examiner then must offer one or more secondary references (or other rationale) that teach the claim features missing from the primary reference or explain why one of skill would add such a feature, such that a modification of the primary reference in view of the missing features would lead to a device having all the claimed features of the invention.

In making the obviousness rejection, the Examiner must also identify a reasonable explanation as to why one of skill in the art would take the features taught by the secondary reference(s) and add those features to the primary reference.

However, there must be some motivation for making the combination that is not the result of improper hindsight. That

is, what is considered obvious must have been obvious to one of skill in the art at the time of the invention.

Turning to the independent claims, the Examiner rejected claim 1 as obvious over SCHMIDT as a primary reference.

The Examiner, on page 6 of the previous Official Action, identified an oral care film, the film comprising tensides, polishing agents, aromatizing agents, and other ingredients, pre-segmented into dosage units, wherein the film includes gelatins, glycerols, natural and synthetic resins and gums.

The Examiner acknowledged that SCHMIDT fails to teach the composition as beads, or that a single bead weighs one gram.

Thus, with respect to claim 1 of the present invention, SCHMIDT fails to teach a homogeneous and non-encapsulated single-dose gel bead providing a gel framework which breaks apart when the gel bead is disrupted by a person in a personal oral, dental, or skin care procedure.

Therefore, the question as to obviousness is:

whether it would have been obvious to modify the thin film of SCHMIDT to assume the shape of a gel bead taught by ALEXANDER (see previous Official Action, page 7, second full paragraph).

The answer is no. The modification proposed by the Examiner would defeat the intended function of SCHMIDT, reducing the speed and efficiency in dissolution of the product, and

thereby reducing the utility and effectiveness of the product in both its use as a tooth-cleaning product and its attractiveness as an alternative to traditional toothpaste. Accordingly, the proposed modification would have been non-obvious to one of skill at the time the present invention was made.

SCHMIDT provides active ingredients ready for use as a strip or foil, having a thickness of 0.1-3 mm (column 2, line 48) or as a film of thickness 0.5 mm (column 3, line 52), upon a peelable carrier foil (column 2, line 57) or film made of a disposable substance such as paper. SCHMIDT exclusively refers to the dentifrice as a foil or film (e.g., column 2, line 47), and that it is introduced to the mouth by being placed on a moistened toothbrush (column 3, lines 2-6) which causes dissolution to commence even before the toothbrush enters the user's mouth (column 3, lines 4-5). No time is disclosed as to how long the film takes to completely dissolve after insertion into the mouth, but is clear that "that intensive movement" of the toothbrush is part of the dissolving process (see column 3, line 8-9).

SCHMIDT, significantly, does not teach the use of agar (agar-agar) as a disruptable carrier for the active ingredients of a dentifrice. Instead, SCHMIDT relies on a quick dissolving action as would be expected of a broad film one half millimeter thick and exposed on both sides. Although SCHMIDT does not disclose a time for dissolution, the reference suggests that full

dissolution requires at least some brush activity (see column 3, line 9). Therefore, dissolution cannot be immediate, which is no surprise given the high concentration of either amylogum or gelatin (column 3, lines 40-48), and given that the product must i) adhere to the brush prior to insertion into the mouth, but ii) maintain enough structure so as not to completely dissolve prior to the insertion.

One of skill would have readily appreciated that a film having a thickness of 0.5 mm and 35 x 8 mm immersed in water will be completely dissolved once 0.25 mm of material has dissolved from each surface. A shape of a thin strip or film is ideal for this method of dissolution, as a flat composure enables the greatest surface area with respect to a given volume. Indeed, SCHMIDT requires that a dosage of the film is to adhere to the toothbrush and swell once placed onto a moistened toothbrush by means of the moisture contact (column 3, lines 2-6). Thus, SCHMIDT's product pre-dissolves in a first mode, whereas full dissolution takes place afterward so that the components can develop their full activity, and hence, after use and subsequent mouth washing with water, no remains are retained in the mouth (column 3, lines 9-12).

A gel shape would defeat this purpose. A sphere or semi-sphere is a shape with a minimized surface area for the volume. That is, the surface area of the strip or film disclosed by SCHMIDT is much greater than that of even a semi-spherical gel

having the same volume. Hence, one of skill would appreciate that the rate of dissolution of SCHMIDT's foil or film is greatly impacted by modifying the shape from a flat profile.

The Official Action states that the active ingredients would be released just as they would in strip form because the active ingredients are released when the outside of a bead shape is dissolved. The Official Action states "no matter the shape, it is reasonable to conclude that the composition will perform the same."

Clearly, based at least on the arguments presented above, this is not true. On the contrary, a spherical shape is the worst geometry with which to modify SCHMIDT given SCHMIDT's disclosed necessity for controlled dissolution (partial dissolution on the wet brush, full dissolution in the mouth), and SCHMIDT's disclosed relationship between dissolution and exposed surface area. One of skill would therefore reasonably conclude that SCHMIDT, modified to take the form of a spherical or semi-spherical gel, would fail to properly dissolve to adhere to the toothbrush (and, e.g., fall off the toothbrush), and would fail to completely dissolve in the mouth within a reasonable amount of brushing time (leaving undissolved residue, wasted and unpleasant as it rolls around loosely in the mouth cavity).

Therefore, as the proposed modification of SCHMIDT renders it unsuitable for its intended purpose, it is respectfully submitted that one of skill would have found it non-

obvious to combine the references SCHMIDT and ALEXANDER, and accordingly, the present invention as recited in claim 1 is non-obvious over the references.

It is respectfully submitted that independent claim 23 is patentable over SCHMIDT and ALEXANDER at least for the same reasons set forth above as to claim 1.

It is further respectfully submitted that claims depending from claims 1 and 23 are patentable at least for depending from patentable parent claims.

For example, SCHMIDT and ALEXANDER fail to render obvious claim 3. Although ALEXANDER discloses the use of agar, the use of agar is inappropriate in the quick dissolving foil or film of SCHMIDT. At best, the use of agar in SCHMIDT would require a concentration by weight far above 2%.

SCHMIDT and ALEXANDER fail to render obvious claim 5. At best SCHMIDT suggests gelatin in combination with starch as a film-forming agent. However, the concentration of gelatin (column 2, lines 35-39) at 16-20% clearly exceeds 4%, as recited in claim 5.

SCHMIDT and ALEXANDER fail to render obvious claim 8. At best, SCHMIDT discloses ingredients by weight, which together exceed that recited in the claim (column 3, lines 40-48), and dimensions (column 3, lines 50-53), wherein the density is yet undisclosed. Hence, SCHMIDT fails to disclose the mass recited in claim 8.

SCHMIDT and ALEXANDER fail to render obvious claims 24-25, based on the same reasonings as for claim 3, above.

SCHMIDT and ALEXANDER fail to render obvious claim 26, based on the same reasonings as for claim 5, above.

SCHMIDT and ALEXANDER fail to render obvious claim 27, based on the same reasonings as for claim 8, above.

Based on the facts presented above, it is respectfully submitted that the claims are patentable over SCHMIDT and ALEXANDER. Reconsideration and withdrawal of the rejection under Section 103 are respectfully requested.

Conclusion

From the foregoing, it will be apparent that Applicants have fully responded to the November 13, 2008 Official Action and that the claims as presented are patentable. In view of this, Applicants respectfully request reconsideration of the claims, as presented, and their early passage to issue.

In order to expedite the prosecution of this case, it is requested that the Examiner telephone the attorney for Applicants at the number set forth below if the Examiner is of the opinion that further discussion of this case would be helpful.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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